

REMARKS

The Examiner rejected claims 1-23 under 35 U. S. C. § 102 and 35 U. S. C. § 103. Claims 21-23 have been cancelled without prejudice, so the rejection of these claims is moot. As to claims 1-20, the Examiner relied upon any one of Eifler U. S. Patent 4,233,033 (hereinafter Eifler), Yasuda U. S. Patent 4,244,918 (hereinafter Yasuda '918), Yasuda U. S. Patent 4,277,439 (hereinafter Yasuda '439), Yasuda U. S. Patent 4,303,613 (hereinafter Yasuda '613), Tien U. S. Patent 4,387,359 (hereinafter Tien), Raymond U. S. Patent 4,571,543 (herinafter Raymond), Wohltjen U. S. Patent 4,572,900 (hereinafter Wohltjen), Stanbro U. S. Patent 4,935,207 (herinafter Stanbro) or Pribat U. S. Patent 5,017,340 (hereinafter Pribat) to support these rejections.

The amended claims and the new claims are limited to Cottrell current-type biosensors wherein the variation in electrical impedance of the analyte reaction zone in response to the application of an analyte, the concentration of which is to be determined, produces a Cottrell current-like profile. Support for these limitations is found in the application as filed, for example, at page 4, lines 22-25.

Because none of Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro or Pribat discloses or suggests a Cottrell current-type biosensing cell assembly or a test cell connected across the distal ends of the conductors, the test cell having an analyte reaction zone with an electrical impedance that varies in response to analyte concentration, the variation in electrical impedance of the analyte reaction zone in response to the application of an analyte, the concentration of which is to be determined, producing a Cottrell current-like profile, the claims as amended herein are not anticipated by, nor would they have been rendered 35 U. S. C. § 103 obvious, in view of any of Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro or Pribat.

The Examiner rejected claims 1-23 under 35 U. S. C. § 103. Claims 21-23 have been cancelled without prejudice, so the rejection of these claims is moot. As to claims 1-20, the Examiner relied upon the combination of Parks U. S. Patent 4,999,582 (hereinafter Parks), H. W. van Rooijen and H. Poppe, "Noise And Drift Phenomena In Amperometric And Coulometric Detectors For HPLC And FIA," Journal Of Liquid Chromatography, 6 (12), 2231-2254 (1983) (hereinafter van Rooijen), and any of Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro or Pribat to support this rejection. The Examiner takes the position that Parks teaches an amperometric biosensor electrode excitation circuit that is substantially similar to the claied device. The Examiner takes the position that the device of Parks has two electrodes (12, 14) forming a measurement loop that

includes a test cell (10) on a substrate (16). The Examiner takes the position that Parks's Fig. 3 illustrates a circuit for applying potential to the electrodes for measurement of an analyte. The Examiner concedes that Parks does not teach a noise cancellation loop to cancel the effects of electromagnetically propagated energy. The Examiner relies upon van Rooijen to teach noise and drift phenomena in amperometric and coulometric detectors. The Examiner observes that van Rooijen discusses noise and drift phenomena in electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis. The Examiner observes that van Rooijen discusses three different methods for ascertaining a relation between the capacitance of the working electrodes of such electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis and the noise generated in such detectors. The three methods noted by the Examiner are: (1) direct correlation of noise with capacitance; (2) time correlation functions; and, (3) electrical simulation of the properties of the cells of such electrochemical detectors with solid electrodes for high-performance liquid chromatography and flow-injection analysis. The Examiner notes that van Rooijen specifically mentions at page 2232 several different causes of drift and noise including temperature fluctuations and electronic equipment. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to which the present invention pertains to incorporate the compensating configurations of any of Eifler, Yasuda '918, Yasuda '439, Yasuda '613, Tien, Raymond, Wohltjen, Stanbro or Pribat into Parks because of the ability to remove interference with the electrochemical signal owing to temperature fluctuations which van Rooijen teaches.

More is required to make out a *prima facie* case of obviousness under 35 U. S. C. § 103 than simply finding the isolated bits and pieces of the claimed arrangement in the prior art.

When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors).

"The factual inquiry whether to combine references must be thorough and searching." Id. It must be based on objective evidence of record. This precedent has been reinforced in

myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) (“a showing of a suggestion, teaching, or motivation to combine the prior art references is an ‘essential component of an obviousness holding’”) (quoting C.R. Bard, Inc., v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998)); In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”); In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (“teachings of references can be combined only if there is some suggestion or incentive to do so.”) (emphasis in original) (quoting ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)).

The need for specificity pervades this authority. See, e.g., In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”); In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) (“even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.”); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination “only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references”).

With respect to Lee’s application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner’s conclusory statements that “the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software” and that “another motivation

would be that the automatic demonstration mode is user friendly and it functions as a tutorial” do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to “[use] that which the inventor taught against its teacher.” W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency’s conclusion.

Deferential judicial review under the Administrative Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings. To the contrary, the Administrative Procedure Act reinforces this obligation. See, e.g., Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 43 (1983) (“the agency must examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”) (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)); Securities & Exchange Comm’n v. Chenery Corp., 318 U.S. 80, 94 (1943) (“The orderly function of the process of review requires that the grounds upon which the administrative agency acted are clearly disclosed and adequately sustained.”).

In its decision on Lee’s patent application, the Board rejected the need for “any specific hint or suggestion in a particular reference” to support the combination of the Nortrup and Thunderchopper references. Omission of a relevant factor required by precedent is both legal error and arbitrary agency action. See Motor Vehicle Manufacturers, 463 U.S. at 43 (“an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem”); Mullins v. Department of Energy, 50 F.3d 990, 992 (Fed. Cir. 1995) (“It is well established that agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action.”). As discussed in National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp., 817 F.2d 74, 75 (9th Cir. 1987), an agency is “not free to refuse to follow circuit precedent.”

The foundation of the principle of judicial deference to the rulings of agency tribunals is that the tribunal has specialized knowledge and expertise, such that when reasoned findings are made, a reviewing court may confidently defer to the agency’s application of its knowledge in its area of expertise. Reasoned

findings are critical to the performance of agency functions and judicial reliance on agency competence. See Baltimore and Ohio R. R. Co. v. Aberdeen & Rockfish R. R. Co., 393 U.S. 87, 91-92 (1968) (absent reasoned findings based on substantial evidence effective review would become lost “in the haze of so-called expertise”). The “common knowledge and common sense” on which the Board relied in rejecting Lee’s application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency’s obligation. This court explained in Zurko, 258 F.3d at 1385, 59 USPQ2d at 1697, that “deficiencies of the cited references cannot be remedied by the Board’s general conclusions about what is ‘basic knowledge’ or ‘common sense.’” The Board’s findings must extend to all material facts and must be documented on the record, lest the “haze of so-called expertise” acquire insulation from accountability. “Common knowledge and common sense,” even if assumed to derive from the agency’s expertise, do not substitute for authority when the law requires authority. See Allentown Mack, 522 U.S. at 376 (“Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the Board must be required to apply in fact the clearly understood legal standards that it enunciates in principle . . .”)

The case on which the Board relies for its departure from precedent, In re Bozek, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969), indeed mentions “common knowledge and common sense,” the CCPA stating that the phrase was used by the Solicitor to support the Board’s conclusion of obviousness based on evidence in the prior art. Bozek did not hold that common knowledge and common sense are a substitute for evidence, but only that they may be applied to analysis of the evidence. Bozek did not hold that objective analysis, proper authority, and reasoned findings can be omitted from Board decisions. Nor does Bozek, after thirty-two years of isolation, outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and Patent Appeals that determination of patentability must be based on evidence. This court has remarked, in Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1421 (Fed. Cir. 1999), that Bozek’s reference to common knowledge “does not in and of itself make it so” absent evidence of such knowledge.

In re Lee, 61 U. S. P. Q. 2d 1430, 1433-1435, (Fed. Cir. Jan. 18, 2002).

Applicant submits that the combination relied upon by the Examiner does not meet the requirements recognized by In re Lee to make out a *prima facie* case of 35 U. S. C.

§ 103 obviousness. Accordingly, Applicant submits that the 35 U. S. C. § 103 rejection of claims 1-20 is overcome.

Please charge any fees which may be necessary to constitute this a timely response to the March 13, 2003 official action, or credit any overpayment, to Applicant's undersigned counsel's deposit account 10-0435 with reference to our file 5727-72828. A duplicate copy of this authorization is enclosed. Accordingly, Applicant submits that this application is in condition for favorable consideration, culminating in allowance. Such action is respectfully requested.

Respectfully submitted,



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